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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/120,030	07/21/1998	BETH P GOLDSTEIN	7732-022-27	1743

7590 09/17/2004  
PIPER RUDNICK, LLP  
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Washington, DC 20036-2412

EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/120,030	<b>Applicant(s)</b> GOLDSTEIN ET AL.	
	<b>Examiner</b> Michael Borin	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07/20/2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4,5,28,32,35,41-51,56-59 and 61-66 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5,32,41-51,56-59 and 61-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. Response filed 07/20/2004 is acknowledged. There is no change in claim status. Claims 4,5, 28,32,35,41-51,56-59,61-66 are pending. Claims 28,35 remain withdrawn from consideration.

2. "New matter" rejection of claims 61,62,63,64 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's arguments. Examiner acknowledges that eradication of infection by lysostaphin is mentioned in the abstract of invention.

### ***Claim Rejections - 35 USC § 103***

3. Claims 4,5,32,41-51,56-59,61-66 remain rejected under 35 U.S.C. 103(a) as obvious over Zygmunt, and Goldberg and Stark, and further in view of Oldham. The rejection is maintained for the reasons of record as applied to claims 4,5,32,41-60, and further in view of the following.

Examiner maintains that there is only a marginal difference between dosages described as effective on dogs in Goldberg and dosage range as instantly claimed. The dosage is in the same order, and it would be *prima facie* to an artisan that dosage demonstrated to be effective in dogs should be fine-tuned for use in humans. Absent some teaching to the contrary (which is still not offered by

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applicant), determination of particular ranges employed is within the skill of the ordinary worker as a part of the process of normal optimization. Further, as the instant claims are drawn to recombinant lysostaphin, and Oldham demonstrated that recombinant lysostaphin has antimicrobial activity similar to the natural product, it would be obvious, again, that the dosage of recombinant lysostaphin would be in the same range as for natural lysostaphin, but must be fine-tuned. Furthermore, it is well known that actual activity of antibiotics is batch-dependent - this is why activity of antibiotics is often expressed in units of activity, rather<sup>1</sup> than in absolute units like mg/kg/day as in the instant claims - and, again, it would be obvious that determination of particular ranges of recombinant lysostaphin for use in humans would be within the skill of the ordinary worker as a part of the process of normal optimization. Finally, instant specification itself supports the obviousness to determine a particular dosage range as it states that "suitable dosages and regiments of lysostaphin may vary with the severity of infection and the sensitivity of the infecting organism" (see p. 10, lines 5-9).

In regard to the use of combined therapy, see discussion of the Zygmunt reference.

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<sup>1</sup>See, for example Schuhardt et al. J. Bacteriol., vol. 88, 1964, p. 815, lines 4-8.

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4. Claims 32,42,43,46,47,50,51,54,55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zygmunt, and Goldberg and Stark, and Oldham as applied above, and further in view of Dixon. The rejection is maintained for the reasons of record.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by

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telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

9/14/04

mlb

MICHAEL BORIN, P.R.E.  
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read 'Michael Borin', is written over the printed name and title.